A successful pregnancy and birth outcome with dolutegravir-based ART

Doctors in Rome, Italy, recently reported the successful use of dolutegravir-based potent combination anti-HIV therapy (ART) to prevent HIV transmission from mother to child. There were no birth defects detected in the infant. Although these results are good, much more research analysing other pregnancies will be needed to determine the safety of dolutegravir in pregnancy.

Case details

A woman infected at birth had what her doctors described as “a long history of exposure to [anti-HIV therapy]” that began in her early childhood. Over the years her doctors found that she had “experienced many virological failures.” This led to strains of HIV in her body that had developed the ability to resist many drugs from all major classes. Such strains are called multidrug resistant (MDR).

In the 18 months before she became pregnant, the woman’s anti-HIV regimen was as follows:

- Truvada (tenofovir 300 mg and FTC 200 mg) one tablet daily
- darunavir (Prezista) 600 mg twice daily
- low-dose ritonavir (Norvir) 100 mg twice daily
- raltegravir (Isentress) 400 mg twice daily

Despite this regimen, blood tests in April 2013 revealed that her CD4+ count was 12 cells/mm$^3$ and her viral load was 126,000 copies/mL. Resistance testing confirmed that she had MDR-HIV.

Doctors then replaced raltegravir with dolutegravir 50 mg twice daily (the dose used by treatment-experienced patients) and left the rest of her regimen unchanged. Subsequently her CD4+ count rose to 135 cells/mm$^3$ and her viral load fell to less than 40 copies/mL.

In January 2014, the woman expressed a desire to become pregnant despite the concerns of her doctors, perhaps because the safety of dolutegravir in pregnancy was unknown. In March 2014 she became pregnant. At that time her CD4+ count was 262 cells/mm$^3$ and her viral load was again less than 40 copies/mL.

A comprehensive medical team at her local infectious disease clinic stated that they “exhaustively” counselled the woman and her partner about the risks of HIV transmission to the fetus and whether the use of dolutegravir should be interrupted or continued because of its unknown fetal safety. The woman and her partner chose to continue taking dolutegravir.

Tests and scans during pregnancy did not reveal any defects and the fetus developed normally. Shortly before the woman gave birth, blood tests found that her CD4+ count was almost 500 cells/mm$^3$ and her viral load was still less than 40 copies/mL.

In the 37th week of her pregnancy, the woman went into premature labour. Doctors therefore decided to deliver the baby via C-section. While the woman was in labour and delivery, nurses gave her intravenous AZT (zidovudine, Retrovir) as an additional measure to help reduce the risk of HIV transmission to her baby. After birth, the infant received a combination of the drugs AZT + 3TC for the first six weeks of life. This therapy for the baby is considered a form of post-exposure prophylaxis—it helps prevent infection taking hold in the baby should it have been exposed to HIV during the birthing process.

Tests that sought to detect HIV’s genetic material in the baby were negative at birth, one month after and six
months after birth, showing that she was not infected.

Examination by doctors did not find any birth defects and the baby is healthy.

The doctors credited the woman’s excellent adherence to ART and her regular clinic visits to the effort made by the medical staff to nurture a good relationship with her. The Italian team encourages other doctors to “actively” involve HIV-positive women in decision-making around care and treatment during pregnancy. This advice is especially important because not all women can plan their pregnancies and receive pre-pregnancy counselling.

The report by the Italian doctors is a very positive one. However, readers should note that data from many HIV-positive pregnant women is needed before the safety of dolutegravir in pregnancy is known.

—Sean R. Hosein

REFERENCE:


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